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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,767	11/20/2003	Jean-Francois Meritet	046658/271691	8380

826 7590 12/29/2006  
ALSTON & BIRD LLP  
BANK OF AMERICA PLAZA  
101 SOUTH TRYON STREET, SUITE 4000  
CHARLOTTE, NC 28280-4000

EXAMINER
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HISSONG, BRUCE D

ART UNIT	PAPER NUMBER
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1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/717,767	<b>Applicant(s)</b> MERITET ET AL.	
	<b>Examiner</b> Bruce D. Hissong, Ph.D.	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 3-9 and 11-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some    \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                            |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application                  |
| Paper No(s)/Mail Date <u>11/20/2003</u> .  | 6) <input checked="" type="checkbox"/> Other: <u>Sequence comparisons 1 and 2.</u> |

## DETAILED ACTION

### **Election/Restrictions**

1. Applicant's election of Group I, claims 1-2 and 10, in the reply filed on 12/1/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-25 are currently pending. Claims 3-9 and 11-25 are withdrawn as non-elected subject matter, and claims 1-2 and 10 are the subject of this office action.

### **Information Disclosure Statement**

The information disclosure statement received on 11/20/2003 has been fully considered.

### **Specification**

1. The disclosure is objected to because of the following informalities: Page 6, lines 2-3 states that SEQ ID NO: 1 is the amino acid sequence of human protein HuIFRG 55.1 *and* its encoding cDNA. It is not clear how a single sequence can be both an amino acid sequence and a cDNA (polynucleotide) sequence.

Appropriate correction is required.

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Specifically, an embedded hyperlink appears on page 11, line 21. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

3. The use of the trademarks "Message Clean<sup>TM</sup>" (p. 19, lines 26-27), and "ABI PRISM<sup>TM</sup>" (p. 20, line 17) has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of

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trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

**Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility, or a well-established utility. The claims are drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 2, or variants or fragments of the polypeptide set forth in SEQ ID NO: 2, and a pharmaceutical composition comprised of said polypeptide, variants, or fragments. The specification of the instant application discloses that the polypeptide encoded by SEQ ID NO: 2, termed HulFRG 55.1, is a novel, interferon (IFN)- $\alpha$ -induced protein.

The Applicants assert that because expression of the polypeptide of SEQ ID NO: 2 is induced by IFN- $\alpha$ , the polypeptide of SEQ ID NO: 2, or variants or fragments thereof, is therefore useful in methods of predicting responsiveness to IFN- $\alpha$  therapy. This purported utility is not specific, substantial, or credible because there is no disclosure of any specific level of expression of the polypeptide of SEQ ID NO: 2, or any variant or fragment thereof, that would correlate with effectiveness of any IFN- $\alpha$  therapy. Furthermore, it is unlikely that expression of SEQ ID NO: 2, or variants or fragments thereof, would predict the efficacy of IFN- $\alpha$  treatment in all diseases for which administration of IFN- $\alpha$  would be indicated. Even if the instant specification did explicitly teach how to use the claimed polypeptide in such a way, this utility is still not specific to the polypeptide of SEQ ID NO: 2, or variants or fragments thereof, because many IFN- $\alpha$ -inducible proteins are well-known in the art and could conceivably be used in such a manner.

The specification also teaches that the claimed polypeptide of SEQ ID NO: 2, or variants or fragments thereof, can be used therapeutically to treat a number of diseases or conditions, such as those disclosed on page 3. However, the specification does not disclose any specific biological activity of the polypeptide of SEQ ID NO: 2, or any variant or fragment thereof, and

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also does not provide information such as tissue distribution, or identity of any receptor. There is also no disclosure of any disease or condition associated with abnormal expression or function of the protein of SEQ ID NO: 2, or any variant or fragment thereof. The specification asserts that because the polypeptide of SEQ ID NO: 2 is induced by IFN- $\alpha$ , it plays a role in immune regulation, or possesses anti-viral or anti-tumor activity. However, the specification provides no teaching, data, or examples to support such biological roles. Therefore, the specific function of this protein would be speculative and significant, further experimentation would be required of the skilled artisan to identify a dysfunction or disease that is associated with the polypeptide (SEQ ID NO: 2).

Thus, the instant claims are drawn to a polypeptide, or variants or fragments thereof, that has an undetermined function or biological significance. There is no actual and specific significance that can be attributed to the polypeptide of SEQ ID NO: 2, or variants or fragments thereof, that is identified in the specification. For this reason, the instant invention is incomplete. In the absence of knowledge of the biological significance of this protein, there is no immediately obvious patentable use for it. Since the instant specification does not disclose a "real-world" use for the polypeptide of SEQ ID NO: 2, or any variant or fragment thereof, the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful.

The instant situation is directly analogous to that of which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (SUS. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which required that an invention must have either an immediate obvious or fully disclosed "real-world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility," "[u]nless and until a process is refined and developed to this point - where specific benefit exists in currently available form - there is insufficient justification for permitting an applicant to engross what may prove to be a broad field," and "a patent is not a hunting license," "[i]t is not a reward for the search, but compensation for its successful conclusion."

There is little doubt that, after complete characterization, this protein, and therefore, the claimed antibody, will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and, until it has been undertaken, the Applicants' claimed invention is incomplete.

The specification also discloses, and claim 2 is drawn to, production of antibodies specific for the polypeptide of SEQ ID NO: 2, or a variant or fragment thereof. However, the asserted utility of SEQ ID NO: 2 in the production of specific antibodies is not specific,

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substantial, or credible. Because the polypeptide of SEQ ID NO: 2 has not been adequately characterized in the instant specification, and one of ordinary skill in the art would not know what the claimed polypeptide does, or how to use it, a skilled artisan would also therefore not know how to use any specific antibody for the polypeptide of SEQ ID NO: 2.

**Claim Rejections - 35 USC § 112, first paragraph - enablement**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-2 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility, or a well-established utility (see above). Claims 1-2 and 10 are therefore also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility, or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

2. Claims 1-2 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprised of SEQ ID NO: 2, does not reasonably provide enablement for any variant or fragment of SEQ ID NO: 2 with a substantially similar function selected from immunomodulatory activity, anti-viral activity, or anti-tumor activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of claims. Ex Parte Forman, (230 USPQ 546 (Bd. Pat. App. & Int. 1986); In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The claims of the instant invention are drawn to an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2, and are also drawn to any variant or fragment

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thereof that has a substantially similar function selected from immunomodulatory, anti-viral, or anti-tumor activity. As stated above in the rejection under 35 U.S.C. 101, the specification does not teach any specific biological activity for the polypeptide of SEQ ID NO: 2, and the specification also does not teach, or provide any examples of any variant of SEQ ID NO: 2, naturally-occurring or otherwise, or any fragment of SEQ ID NO: 2, that retains has any biological activity. As written, the breadth of the claims is excessive because the claims are drawn to numerous possible variants and fragments of SEQ ID NO: 2 that could have any immunomodulatory, anti-viral, or anti-tumor activity. However, because the polypeptide of SEQ ID NO: 2 does not have a disclosed biological activity, one of ordinary skill in the art would not be able to predict how to make, and then use, any variant or fragment of SEQ ID NO: 2 that has any biological activity. Even if the polypeptide of SEQ ID NO: 2 had a disclosed biological function, one of ordinary skill in the art would not be able to predict which of the many possible fragments, or variants having at least 60% identity to SEQ ID NO: 2 (see p. 7, lines 4-10), would retain the desired biological activity.

It is known in the art that even single amino acid changes or differences in the amino acid sequence of a protein can have dramatic effects on the protein's function. As an example of the unpredictable effects of mutations on protein function, Mickle *et al* (Med. Clin. North Am., 2000, Vol. 84(3), p. 597-607) teaches that cystic fibrosis is an autosomal recessive disorder caused by abnormal function of a chloride channel, referred to as the cystic fibrosis transmembrane conductance regulator (CFTR – p. 597). Several mutations can cause cystic fibrosis, including the G551D mutation. In this mutation, a glycine replaces the aspartic acid at position 551, giving rise to the cystic fibrosis phenotype. In the most common cystic fibrosis mutation,  $\Delta$ -F508, a single phenylalanine is deleted at position 508, giving rise to the cystic fibrosis phenotype. Thus, even the substitution or deletion of a single amino acid can have dramatic and *unpredictable* effects on the function of the protein. Therefore, even if the polypeptide of SEQ ID NO: 2 had a disclosed function or biological activity, one of ordinary skill in the art would not be able to predict the effects of modifying or mutating various amino acids in order to create a fragment or a variant with at least 60% identity to the polypeptide of SEQ ID NO: 2. Such a determination would require further, undue experimentation on the part of the claimed artisan, who would first have to identify an activity of the polypeptide of SEQ ID NO: 2, then determine which regions or amino acids of SEQ ID NO: 2 could be altered or deleted to create a fragment or variant that still retains biological activity.

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Claim 2 is drawn to a variant or fragment of SEQ ID NO: 2 suitable for raising antibodies specific for the polypeptide of SEQ ID NO: 2, or any naturally-occurring variant thereof. The breadth of the claim is excessive because as written, the claim encompasses polypeptides or peptides for creating antibodies specific for a large number of potential variants. As stated above, the specification does not provide guidance or examples showing any naturally-occurring variant of SEQ ID NO: 2. Without such guidance or examples showing the sequence or structure of such a naturally-occurring variant, one of ordinary skill in the art would not be able to predict which polypeptide or peptide sequences must be used in order to raise an antibody that is specific for any naturally-occurring variant of SEQ ID NO: 2. Thus, a skilled artisan would require further, undue experimentation to make and use any fragment or variant of SEQ ID NO: 2 that could be useful to raise an antibody that would specifically recognize any naturally-occurring variant of SEQ ID NO: 2.

**Claim Rejections - 35 USC § 112, first paragraph – written description**

Claims 1-2 and 10 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated polypeptide comprising any variant or fragment of the polypeptide of SEQ ID NO: 2, or variants or fragments of SEQ ID NO: 2 that are useful for raising antibodies specific for a naturally-occurring variant of SEQ ID NO: 2. The claims do not require the fragment or variants of SEQ ID NO: 2 of the instant invention to have any particular structure other than be a fragment, of any size or SEQ ID NO: 2, or alternatively be a variant with at least 60% identity to SEQ ID NO: 2 (see p. 7, lines 4-10). The claims are thus drawn to a genus of polypeptides, defined only by percent identity to SEQ ID NO: 2, that has not been adequately described in the specification.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the



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claims is a requirement that the claimed fragments or variants be a fragment of the polypeptide of SEQ ID NO: 2, exhibit at least 60% identity to the polypeptide of SEQ ID NO: 2, or be a fragment or variant suitable for raising an antibody specific for any naturally-occurring variant of SEQ ID NO: 2. There is no identification of any particular region, domain, or amino acid residue(s) that must be conserved in order to maintain any function. Accordingly, in the absence of sufficient distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO:2, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

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**Claim Rejections - 35 USC § 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 10 are indefinite because the elements recited in the claim do not constitute proper Markush groups. The claims are indefinite in the alternative use of "and/or" because it is not clear what controls which of these limitations. See MPEP § 2173.05(h).

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-2 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang *et al* (WO 01/46256 – cited in the information disclosure statement received on 11/20/2003). The claims of the instant invention are drawn to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 2, or variants or fragments having substantially similar function selected from immunomodulatory, anti-viral, or anti-tumor activities (claim 1), and a pharmaceutical composition comprising said polypeptide and a pharmaceutically acceptable carrier or diluent (claim 10). The claims are further drawn to a variant or fragment of the polypeptide of SEQ ID NO: 2 that is suitable for raising specific antibodies for the polypeptide of SEQ ID NO: 2 or naturally-occurring variants thereof (claim 2).

Tang *et al*, which claims priority to provisional application 60/172,968 (filed on 12/21/1999), discloses a polypeptide that is 100% identical to SEQ ID NO: 2 of the instant application. Specifically, SEQ ID NO: 7 of Tang *et al* is 100% identical to SEQ ID NO: 2 of the instant application (see sequence comparison 1). Tang *et al* claims an isolated polypeptide having the sequence of SEQ ID NO: 7, active fragments thereof, or an immunogenic fragment thereof (see claim 1). Thus, Tang *et al* discloses the complete sequence of SEQ ID NO: 2 of the instant application, as well as biologically active fragments, and immunogenic fragments

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which would be suitable for raising antibodies. Therefore, Tang *et al* meets the limitations of claims 1-2 of the instant application. Tang *et al* also teaches a pharmaceutical composition comprised of the polypeptide of SEQ ID NO: 7 and a pharmaceutically acceptable excipient (see claim 16 of Tang *et al*), and thus meets the limitations of claim 10 of the instant application. It is also noted that provisional application 60/172,968 also discloses a sequence (SEQ ID NO: 7) that is 100 identical to SEQ ID NO: 2 of the instant application, and also claims fragments of this polypeptide and a pharmaceutical composition of said polypeptide (see claims 1 and 15, respectively).

2. Claims 1-2 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Edwards *et al* (US 6,783,961 – filed on 2/24/2000 and claiming priority to provisional application 60/122,487, filed on 2/26/1999). The subject matter of the claims of the instant invention is discussed *supra*. Edwards discloses a sequence that is 100% identical to amino acids 132-213 of SEQ ID NO: 2 of the instant invention (see sequence comparison 2), and thus teaches a fragment of the polypeptide of SEQ ID NO: 2. Although Edwards *et al* does not specifically teach that this fragment exhibits immunomodulatory, anti-viral, or anti-tumor activity, it is noted that the term immunomodulatory is broad and not defined by the claims of the instant specification. The fragment taught by Edwards *et al* would be expected, in the absence of evidence to the contrary, to be “immunomodulatory” by inducing an antibody response when administered to an appropriate host. Furthermore, use of this fragment as an immunogen would be expected to produce antibodies that would recognize the polypeptide of SEQ ID NO: 2. Therefore, the fragment taught by Edwards *et al* meets the limitations of claims 1-2 of the instant application. Finally, Edwards *et al* teaches pharmaceutical compositions comprised of polypeptides/peptides disclosed therein (see Examples 25 and 31), and thus meets the limitations of claim 10 of the instant application.

### **Conclusion**

No claim is allowable.

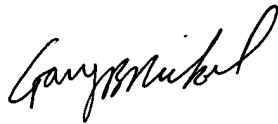
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be

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reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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GARY B. NICKOL, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

# SEQUENCE COMPARISON 1

## RESULT 1

AAE04764

ID AAE04764 standard; protein; 490 AA.

XX

AC AAE04764;

XX

DT 10-SEP-2001 (first entry)

XX

DE Human vesicle trafficking protein-7 (VETRP-7) protein.

XX

KW Human; vesicle trafficking protein-7; VETRP-7; vaccine; cystic fibrosis;

KW glucose-galactose malabsorption syndrome; hypercholesterolaemia; goitre;

KW diabetes mellitus; diabetes insipidus; hyperglycaemia; hypoglycaemia;

KW Grave's disease; Cushing's disease; Addison's disease; AIDS; allergy;

KW ulcerative colitis; gastrointestinal disorder; asthma; hay fever; gout;

KW autoimmune disease; inflammatory disease; bowel disease; osteoporosis;

KW multiple sclerosis; rheumatoid arthritis; psoriasis; anaemia; cancer;

KW pancreatitis; Crohn's disease; glomerulonephritis; atherosclerosis;

KW Goodpasture's syndrome; Hashimoto's thyroiditis; gene therapy; virucide;

KW systemic lupus erythematosus; dermatitis; nephrotropic; antihelminthic;

KW cerebroprotective.

XX

OS Homo sapiens.

XX

FH Key Location/Qualifiers

FT Domain 368..456

FT /note= "C2 domain"

XX

PN WO200146256-A2.

XX

PD 28-JUN-2001.

XX

PF 21-DEC-2000; 2000WO-US034919.

XX

PR 21-DEC-1999; 99US-0172968P.

PR 23-DEC-1999; 99US-0172066P.

XX

PA (INCY-) INCYTE GENOMICS INC.

XX

PI Tang YT, Yue H, Bandman O, Hillman JL, Baughn MR, Lu DAM;

PI Azimzai Y, Yang J, Burford N, Au-Young J, Reddy R;

XX

DR WPI; 2001-418040/44.

DR N-PSDB; AAD09377.

XX

PT Novel human vesicle trafficking proteins useful for treating and  
PT preventing vesicle trafficking disorders, autoimmune/inflammatory  
PT disorders and cancers.

XX

PS Claim 1; Page 106-107; 144pp; English.

XX

CC The present sequence is human vesicle trafficking protein-7 (VETRP-7)  
CC protein. VETRP is used as vaccine. VETRP is useful for treating a disease  
CC or condition associated with decreased expression of functional VETRP,  
CC such as vesicle trafficking disorders e.g., cystic fibrosis, glucose-  
CC galactose malabsorption syndrome, hypercholesterolaemia, diabetes  
CC mellitus, diabetes insipidus, hyperglycaemia, hypoglycaemia, Grave's  
CC disease, goitre, Cushing's disease, Addison's disease, gastrointestinal  
CC disorders including ulcerative colitis, AIDS, allergies including asthma,  
CC hay fever, autoimmune/inflammatory diseases including inflammatory bowel



SEQUENCE COMPARISON 2

RESULT 2

US-09-513-999C-7623

; Sequence 7623, Application US/09513999C

; Patent No. 6783961

; GENERAL INFORMATION:

; APPLICANT: Dumas Milne Edwards, J.B.

; APPLICANT: Duclert, A.

; APPLICANT: Giordano, J.Y.

; TITLE OF INVENTION: Expressed Sequence Tags and Encoded Human Proteins.

; Patent No. 6783961

; FILE REFERENCE: 59.US2.REG

; CURRENT APPLICATION NUMBER: US/09/513,999C

; CURRENT FILING DATE: 2000-02-24

; PRIOR APPLICATION NUMBER: US 60/122,487

; PRIOR FILING DATE: 1999-02-26

; NUMBER OF SEQ ID NOS: 36681

; SOFTWARE: Patent.pm

; SEQ ID NO 7623

; LENGTH: 82

; TYPE: PRT

; ORGANISM: Homo sapiens

; FEATURE:

; NAME/KEY: UNSURE

; LOCATION: 73

; OTHER INFORMATION: Xaa=Lys or Asn

; FEATURE:

; NAME/KEY: UNSURE

; LOCATION: 74

; OTHER INFORMATION: Xaa=Ala or Pro or Ser or Thr

US-09-513-999C-7623

Query Match 16.1%; Score 408; DB 2; Length 82;

Best Local Similarity 97.6%; Pred. No. 1.7e-35;

Matches 80; Conservative 0; Mismatches 2; Indels 0; Gaps 0;

Qy 132 MYQHISPDLSRRFPFRSEVTRLYGSVCDLRTNKLPGSPGLSKSMFDLTNSSQRFIQRHDS 191

|||||

Db 1 MYQHISPDLSRRFPFRSEVTRLYGSVCDLRTNKLPGSPGLSKSMFDLTNSSQRFIQRHDS 60

Qy 192 LSSVPSSSSSRKNSQGSNRSLD 213

|||||

Db 61 LSSVPSSSSSRKXXQGSNRSLD 82